On-line Supplementary Appendix:

This appendix has been provided by the authors to give the reader additional information about their work.

Acknowledgements

A joint study of the NCIC CTG, SWOG, CTSU and Cancer Research UK, coordinated by the NCIC Clinical Trials Group.

Contents

Figure S1: Treatment algorithm for patient in intermittent androgen deprivation arm to enter off treatment interval.

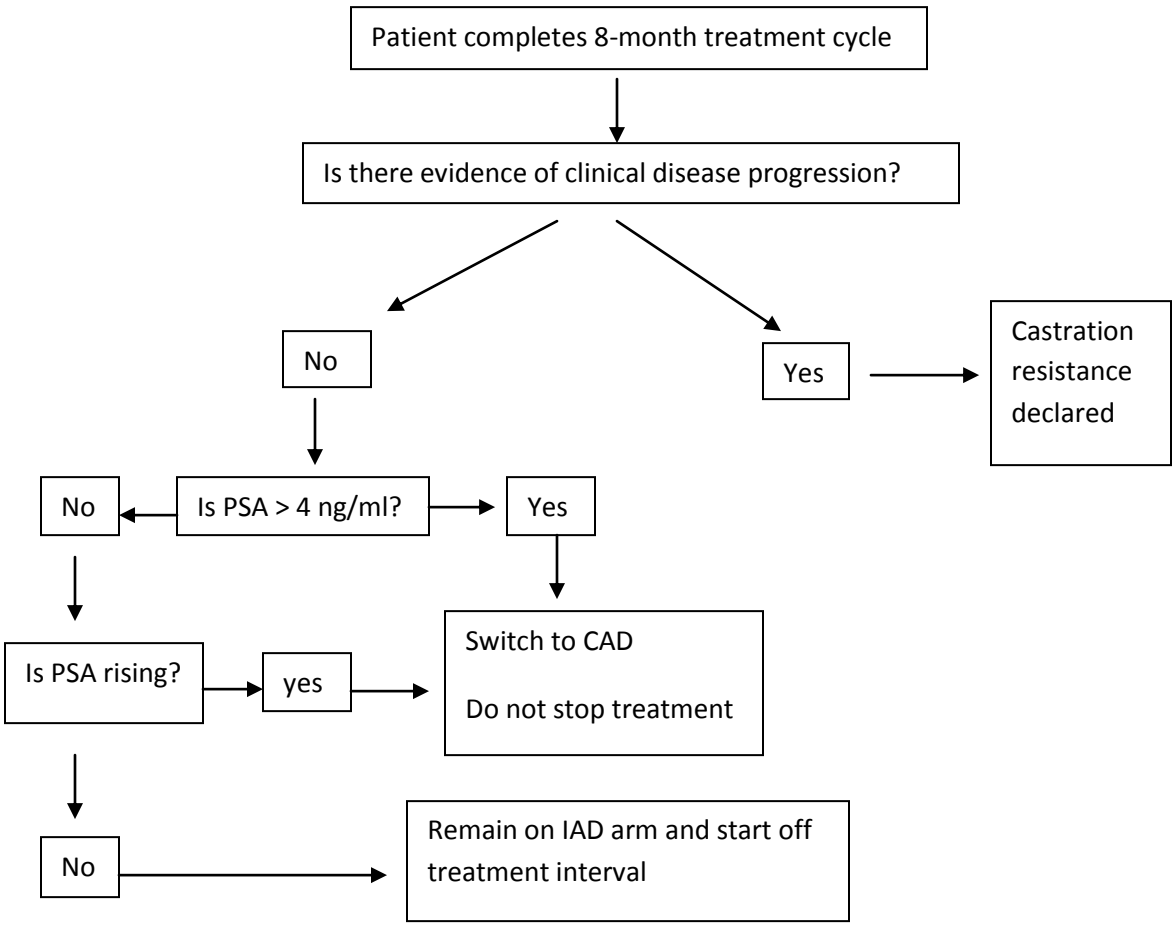
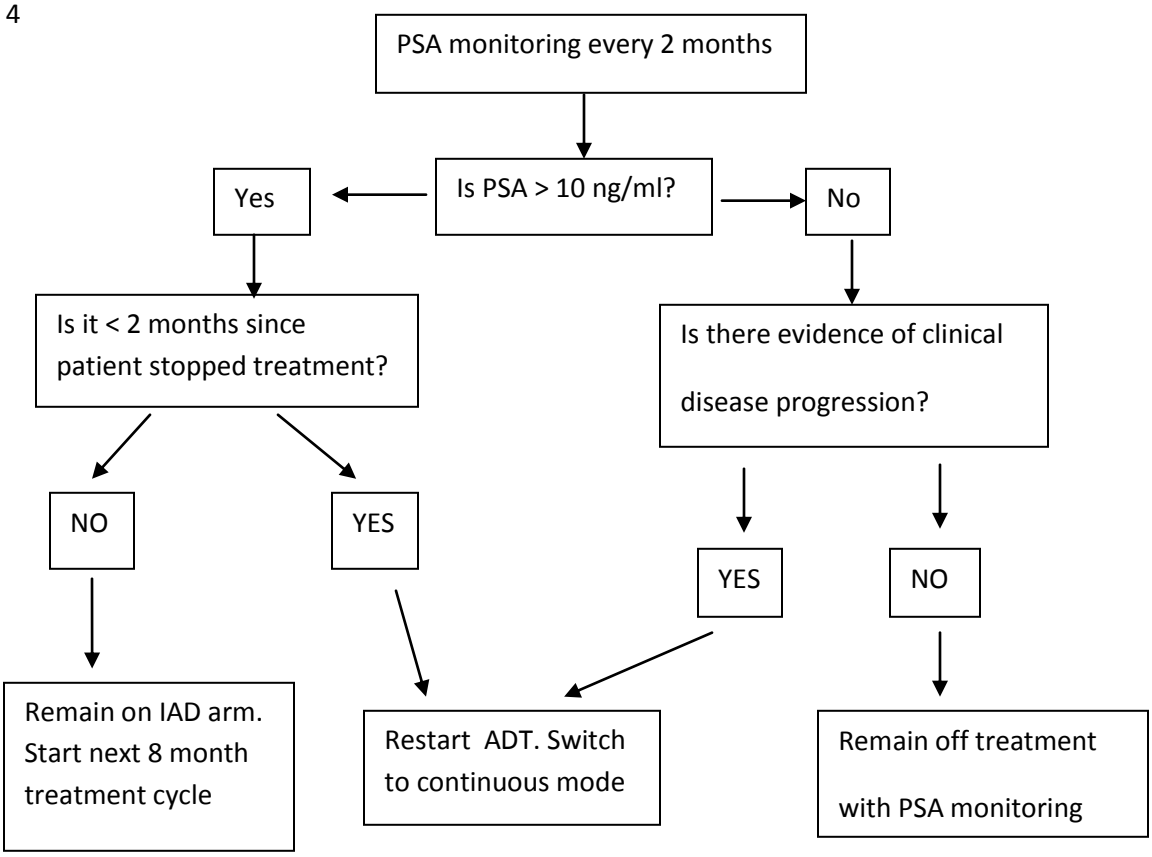
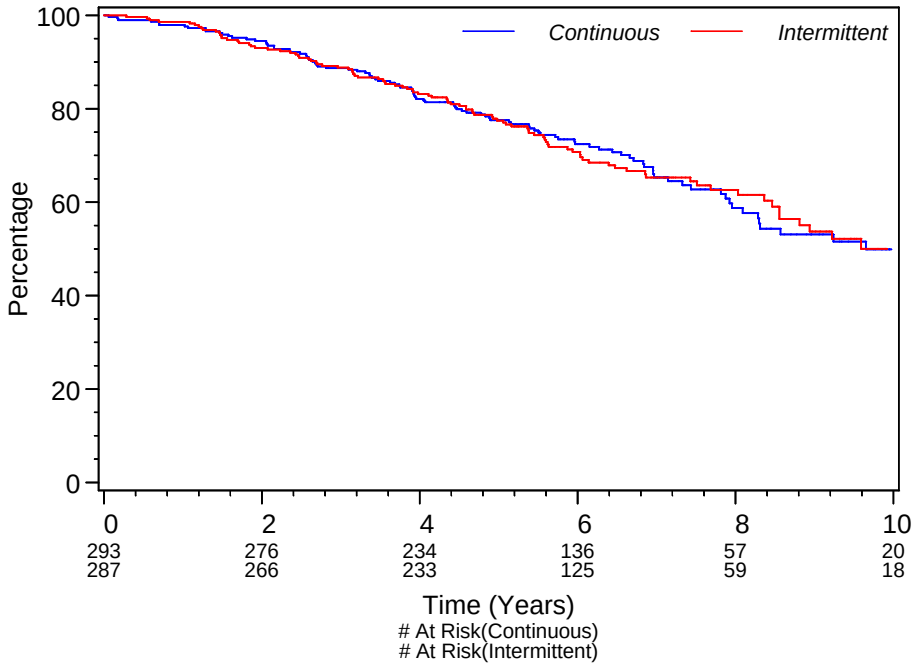


Figure S2: Treatment algorithm for patient in off treatment interval to re-start treatment



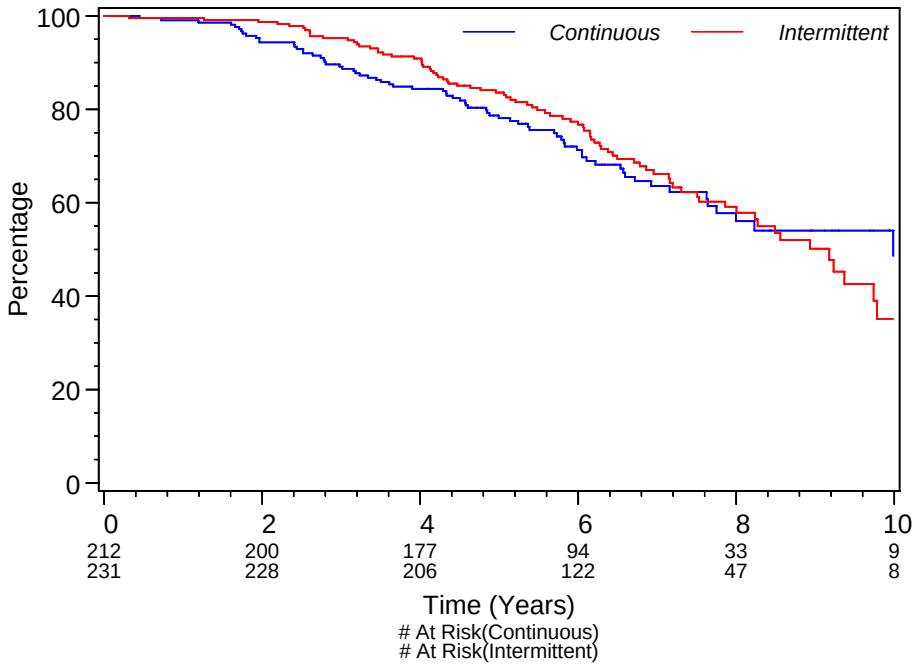
Phase III Trial of Intermittent vs. Continuous Androgen Deprivation

Figure S3a



SUMMARY STATISTICS:

Log-Rank test for equality of groups: p=0.9954
Median for Continuous: 9.65 -95% C.I. (8.09 ,Inf)
Median for Intermittent: 10.06 -95% C.I. (8.56 ,Inf)
Hazard Ratio of Intermittent/Continuous: 1.001 - 95 % C.I. (0.758, 1.321)



SUMMARY STATISTICS:

Log-Rank test for equality of groups: p=0.8849
Median for Continuous: 9.99 -95% C.I. (7.75 ,Inf)
Median for Intermittent: 9.18 -95% C.I. (8.00 ,9.78)
Hazard Ratio of Intermittent/Continuous: 0.977 - 95 % C.I. (0.713, 1.339)

Figure S3b

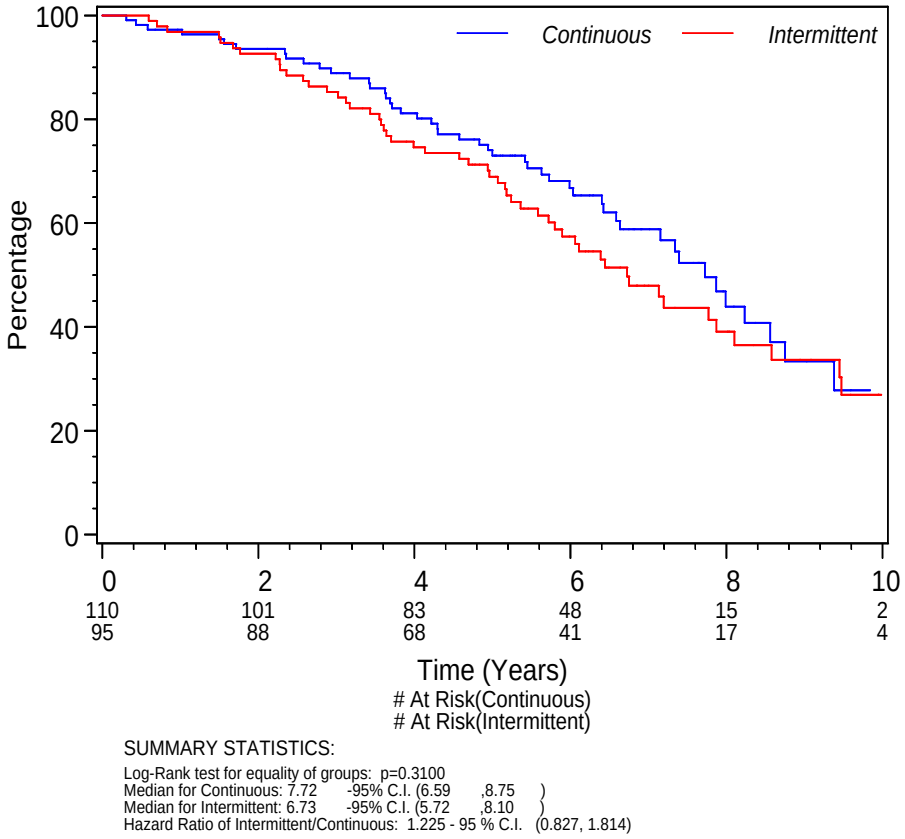
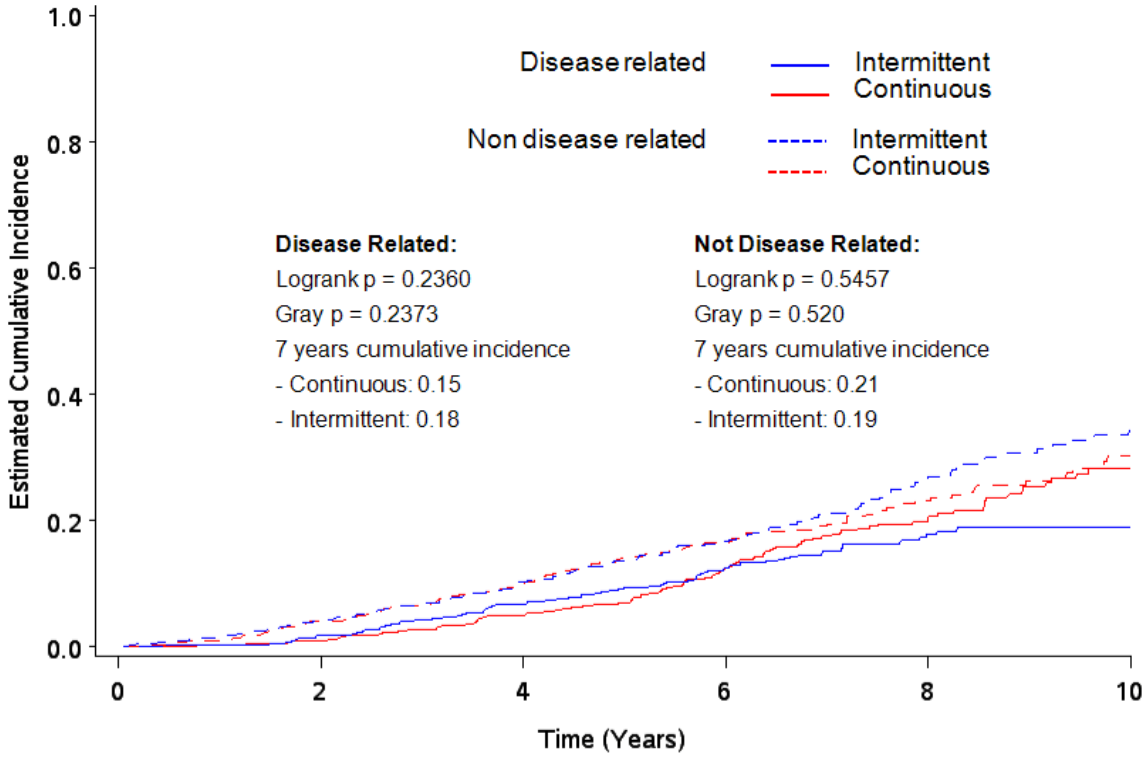


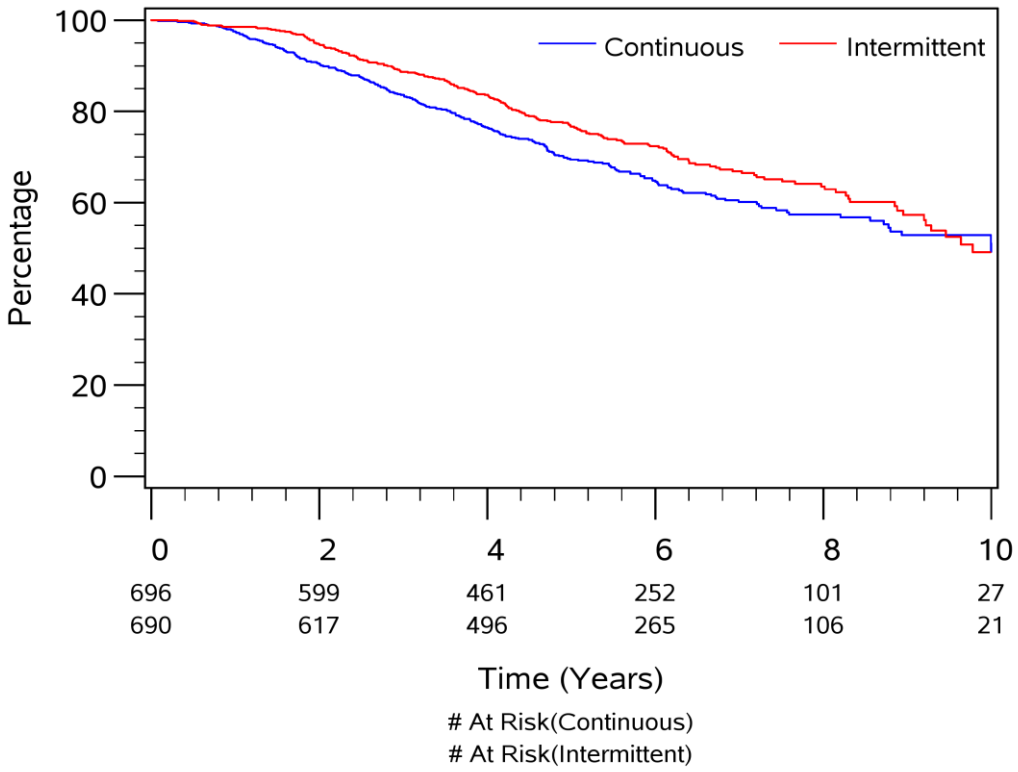
Figure S3c :

Figure S3: Gleason scores were not collected as part of the protocol design but were retrieved retrospectively from stored pathology reports and grouped as follows: unavailable: 9.2%, 2-6: 42.6%, 7: 33.0% and 8-10: 15.2%. Overall survival by treatment arm for 3 Gleason score groups, shows similar OS between treatment arms for Gleason score $\leq$6 (Fig. S3a) and 7 (Fig. S3b), while for Gleason score 8-10 (Fig. S3c), those on IAD had a trend to worse OS (HR of 1.21, p = 0.33). Cox regression model with treatment arm, Gleason score groups and their interaction terms show that there was no differential treatment effect among the 3 groups. The sample size of the study does not have the power to detect a small or moderate difference, but the approximately 14 month greater median survival for Gleason 8-10 receiving CAD suggests caution in this group.

Figure S4: Cumulative Events Plot for Disease Specific Survival (Per Protocol Population)



Phase III Trial of Intermittent vs. Continuous Androgen Deprivation



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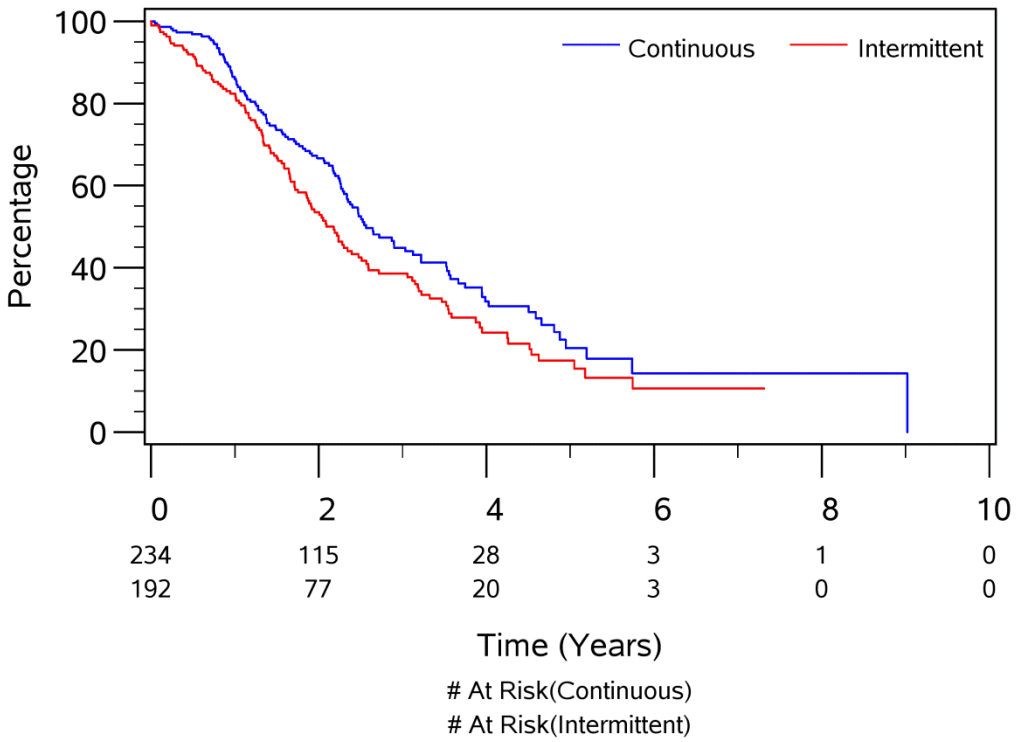

SUMMARY STATISTICS:

Median for Continuous: 2.57 -95% C.I. (2.34 ,3.22)
Median for Intermittent: 2.18 -95% C.I. (1.85 ,2.51)

2

Figure S5: Kaplan-Meier plot by treatment arm of the time to castration resistance (top) and from the time of declaration of castration resistance to death (bottom). There is an approximate 4 month difference observed in favor of the IAD arm in time to castration resistance. The authors believe that this apparent difference is due to the way castration resistance was defined. Men in the IAD arm who became CR while off treatment (rising PSA in the absence of any testosterone recovery) had to be restarted on treatment and have 3 further rises in PSA before declared CR. This delay in declaration of castration resistance in the IAD arm creates an apparent 4-month advantage for the CAD arm in survival after castration resistance.

Table S1: Accrual by Cooperative Group

Region	IAD	CAD	Total
NCIC CTG	469	470	939
SWOG	79	84	163
UK-ICR CTSU	91	91	182
CTSU/RTOG	42	38	80
Total	681	683	1364

CTSU: Clinical Trials Support Unit

RTOG: Radiation Therapy Oncology Group

NCIC CTG: National Cancer Institute of Canada Clinical Trials Group

SWOG: South west Oncology Group

UK-ICR CTSU: United Kingdom Institute of Cancer Research Clinical Trials and Statistics Unit

Table S2

Reasons for Ineligibility

	IAD	CAD	Total
Eligible	681	686	1367
Bone metastases	1		1
Prior malignancy	2	1	3
Elevated AST	1	2	3
Elevated creatinine	1		1
Low testosterone	1	1	2
Prior RT dose low	1		1
Prior HT > 12 months	1	3	4
Multiple reasons	1	2	3

AST : aspartate amino transferase

RT: radiotherapy

HT: hormone therapy

	Intermittent arm				Continuous arm			
Adverse event	Grade 4	Grade 5	Total	Related	Grade 4	Grade 5	Total	Related
Inner ear	1	0	34	1%	0	0	39	0
Edema			94	2%			81	2%
Hypertension	1		50	1%	1		47	2%
Cardiac ischemia	26	2	67	0	36	5	76	1%
Palpitations			9	1%			12	0
Thrombosis	12		27	1%	2		14	0
Hot flashes		1	620	90%			641	93%
Gynecomastia			272	38%			298	42%
Fatigue	2		394	37%	3		385	43%
Chills			17	1%			11	1%
sweating			31	4%			37	4%
Anorexia	3		150	7%	1		116	8%
Constipation			147	5%	1		162	5%
Diarrhea			223	11%			216	11%
Dry mouth			16	1%			13	1%
Flatulence			17	1%			18	1%
Dyspepsia			45	2%			60	2%
Nausea			179	16%			157	13%
Altered taste			11	1%			9	1%
Vomiting			66	3%			51	2%
Urine freq/urg			404	21%			383	23%
Incontinence			136	6%			149	8%
Dysuria			77	3%			42	2%
Retention			101	3%			97	2%
Rectal bleed			43	1%			49	1%
Hematuria		1	86	1%			63	1%
Arthritis	1		203	2%	3		182	2%
Muscle weakness	2		63	2%	2		70	6%
osteoarthritis			43	4%			60	7%
Hyperglycemia			28	1%			23	1%
Anxiety			47	2%			43	3%
Cerebral ischemia	5		13	0	11	3	27	1%
Confusion	3		29	0	1		29	1%
Dizziness			73	2%			91	5%
insomnia			247	19%			272	24%
Memory loss			38	1%			43	1%
Depression	1		63	4%			72	7%
Neuropathy-m			25	0	1		36	1%
Neuropathy-s			72	1%	1		77	3%
Lt-dk adaptation			23	3%			23	3%
Blurred vision			141	13%			167	15%
Night blind			6	1%			9	1%
Photophobia			38	5%			48	7%
Chest pain			49	1%	2		43	1%
Abdo pain	1		78	1%			54	1%
Headache			136	9%			130	10%
Arthralgia			288	6%	1		259	4%
Myalgia			183	4%	1		159	5%
Bone pain	4		242	3%	7		211	3%

Other pain			112	3%	2		75	2%
Cough			77	1%			82	1%
Pneumonitis	3	2	37	1%	5	1	41	1%
Dyspnea	7		216	8%	12	1	217	10%
Alopecia			45	5%			69	9%
Injection site Rx			49	6%			82	11%
Pruritis			19	1%			28	1%
Rash			54	2%	1		52	1%
Testicle atrophy			7	1%			11	1%
Impotence			593	53%			608	53%
Libido			546	55%			541	51%
Weight gain			149	16%			135	17%
Weight loss			67	2%			54	2%

Table S3: All adverse events are listed that were felt by investigators to be possibly, probably or definitely related to protocol treatment. Any grade 4 or 5 events in these categories are listed, as well as the total number (grade 1-5) and the percentage of the population that experienced adverse events in each category felt to be related to the protocol treatment. For example, although 86% of the population experienced impotence, in 53% it was felt to be due to the protocol treatment.

Urine freq/urg: urinary frequency and urgency
Neuropath m/s: sensory and motor
Lt/dk adaptation: light/dark adaptation

Table S4: Phase 2 Trials of Intermittent Androgen Deprivation (*on-line version only)*

Author	Yr	N	F/U mo.	Stage	PSA nadir	Off Rx until	# cycle
Klotz et al[1]	86	20	36	D2	Pre PSA era	Pre PSA era	1-5
Higano et al[2]	96	22	26	PSA failure + D2	<0.1	>10	1-3
Grossfield[3]	98	47	24	T1c-4	0.1-4	>10	1-5
Goldenberg [4]	99	87	65	A2-D2	4	10-20	1-5
Prapotnich[5]	99	566	81	Advanced	<4	>10	1-12
Bouchot[6]	00	44	44	D2	<4	>20	1-2
Strum[7]	00	52	66	T1c-D2	0	>5	1-2
Sciarra[8]	00	51	48	T2-T3 rising PSA	<4		5
Pether[9]	03	102	50	A2-D2	<4	10-20	1-6
De la Taille[10]	03	146	46	T1-4, M1	<4	>10	1-8
Lane[11]	04	75	134	All	<4	>20	1-3
Malone[12]	05	95	69	All	<4	>10	1-7
Cury[13]	06	39	56	T1-3	<4	>10	1-4
Bruchovsky[14]	06	103	50	T1b-T3rising PSA	<4	>10	1-5
Spry[15]	06	250	30	All	<4	>20	1-2

Table S5: Phase 3 Trials of Intermittent Androgen Suppression

Trial	Stage	N	Results
SWOG 9346[16]	D2	1512	Pending
SEUG (Portugal)[17]	T3,4 or M1	914	No difference in OS
AP17/95 (Germany)[18]	T3,4 or M1	335	No diff in TTP or OS
EC507 (Europe)[19]	Post RP rising PSA	167	No diff TTP
Erasmus [20]	M1	366	QOL better
TULP (Netherlands)[21]	T3,4, M1	193	Longer TTP in CAS (NS)
De Leval[22] (Belgium)	T3,4, M1, post RP	68	TTP favoring IAS
Yamanaka[23]	T3,4, adjuvant	188	Short f/u, no diff

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